THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 20

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte THOMAS R. KIRKMAN

Appeal No. 1998-1789
Application 08/473,129[1]

HEARD: Nov. 18, 1999

Before COHEN, ABRAMS, and GONZALES, Administrative Patent Judges.

ABRAMS, Administrative Patent Judge.

DECISION ON APPEAL

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[1]Application for patent filed June 7, 1995. According to appellant, this application is a continuation of Application 08/137,619, filed October 15, 1993, now U.S. Patent No. 5,509,900; which is a continuation-in-part of Application 07/844,715, filed March 2, 1992, now abandoned.

This is an appeal from the decision of the examiner finally rejecting claims 1, 9, 10, 16 and 20-32, which constitute all of the claims remaining of record in the application.

The appellant's invention is directed to a catheter (claims 1, 9, 10, 16, 30 and 31), an assembly including a catheter (claims 22-29), a method of inserting a catheter (claims 20 and 21), and a method of securing a catheter tip (claim 32). The correct copy of the claims on appeal can be found in an appendix to the Examiner’s Answer.

THE REFERENCES

The references relied upon by the examiner to support the final rejection are:

Johnson	3,866,599	Feb. 18, 1975
Corrigan *et al.* (Corrigan)	5,167,634 (filed Aug. 22, 1991)	Dec. 1, 1992

THE REJECTIONS

Claims 1, 9, 10, 16, 20-25 and 27-32 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Johnson.

Claim 26 stands rejected under 35 U.S.C. § 103 as being unpatentable over Johnson in view of Corrigan.[2]

Rather than attempt to reiterate the examiner's full commentary with regard to the above-noted rejections and the conflicting viewpoints advanced by the examiner and the appellant regarding the rejections, we make reference to the Examiner's Answer (Paper No. 14) and the Appellant's Briefs (Paper Nos. 13 and 16).

OPINION

All but one of the appellant's claims stands rejected under 35 U.S.C. § 102(b). The guidance provided by our reviewing court with regard to the matter of anticipation is as follows: Anticipation is established only when a single prior art reference discloses, either expressly or under the principles of inherency, each and every element of the claimed invention (see ***In re Paulsen***, 30 F.3d 1475, 1480-1481, 31 USPQ2d 1671, 1675 (Fed. Cir. 1994) and ***In re Spada***, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990)).

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[2]Rejections of claim 21 under 35 U.S.C. § 112, second paragraph, and claims 1, 9, 10, 16 and 20-31 under the doctrine of double patenting, were overcome, respectively, by amendment and by the filing of a terminal disclaimer.

Anticipation by a prior art reference does not require either the inventive concept of the claimed subject matter or recognition of inherent properties that may be possessed by the reference (see ***Verdegaal Bros., Inc. v. Union Oil Co.***, 814 F.2d 628, 633, 2 USPQ2d 1051, 1054 (Fed. Cir.), ***cert. denied***, 484 U.S. 827 (1987)) or that the reference teach what the applicant is claiming, but only that the claim on appeal "read on" something disclosed in the reference, *i.e.*, all limitations of the claim are found in the reference (see ***Kalman v. Kimberly-Clark Corp.***, 713 F.2d 760, 772, 218 USPQ 781, 789 (Fed. Cir. 1983), *cert. denied*, 465 U.S. 1026 (1984)). It is only necessary that the reference include structure capable of performing the recited function in order to meet the functional limitations of the claim (see ***In re Mott***, 557 F.2d 266, 269, 194 USPQ 305, 307 (CCPA 1977)).

The appellant’s invention is directed to the solution to problems occurring in the placement of catheters in long-term situations such as maintenance dialysis. Objectives of the invention include preventing the tip of the catheter from moving laterally into contact with the wall of the vessel in which it is placed and anchoring the tip of the catheter at a

selected location along the length of the vessel, while at the same time not substantially occluding the vessel such that stenosis or thrombosis can occur. As manifested in claim 1, the invention comprises a catheter having tip immobilizing means on its distal end to "prevent the tip of the catheter from contacting a wall of the blood vessel without substantially obstructing fluid flow of blood through the blood vessel, such that catheter failure due to stenosis or thrombosis at the catheter distal end is reduced." Similar limitations appear in all of the other claims. The examiner's position is that the subject matter of all of the others except claim 26 is anticipated by the catheters shown in Figures 8-11 of Johnson.

Johnson discloses a catheter within which are positioned a plurality of light-conducting fibers. The stated objective of the Johnson invention is to prevent the tips of the light-conducting fibers from contacting the wall of the vessel in which they are installed in order to avoid the creation of artifact by blood flow fluctuations and blood vessel wall reflectance (column 1, lines 32-59). In the embodiments shown in Figures 2-7, 10 and 11, Johnson accomplishes this objective

by terminating the distal end of the fibers short of the end of the catheter, that is, inside the catheter. In the embodiments of Figures 8-11, the tip of the catheter also is provided with elements that are held within the catheter during insertion into the vessel, and which are extended radially outwardly of the catheter when the tip of the catheter is in the vessel. In Figure 8 this comprises an annular sleeve, in Figure 9, a plurality of fingers, in Figure 10, a plurality of wire-supported wings, and in Figure 11, a balloon. These elements also act as an obstruction to blood flow to generate a force on the tip of the catheter in the direction of flow, thereby "flow directing" the catheter along the path of flow (column 4, lines 1-57). There is no explicit teaching in Johnson that the radially extending elements touch the wall of the vessel, although it would appear that they do at least at some time during the operation of the catheter.

There are two structural requirements in claim 1 that in our view are not disclosed or taught by Johnson. The first is that claim 1 recites tip immobilizing means which "maintain the tip of the catheter in a spaced relationship from a blood vessel wall and prevent the tip of the catheter from

contacting a wall of the blood vessel" (emphasis added). While Johnson discloses elements that extend radially outwardly of the tip of the catheter, their functions are to prevent the tips of the light-conducting fibers from contacting the inner wall of the vessel, and to obstruct the flow of blood. There is no explicit teaching in the patent that these elements maintain the catheter spaced from the walls of the vessel and/or prevent contact between the tip of the catheter and the vessel wall. Nor, in our opinion, is there reason to assume that they inherently perform the tasks set forth in the appellant's claim 1 or are even capable of doing so. We arrive at this conclusion for several reasons. First, the patent does not address any problem associated with such occurrences. Second, the patent disclosure does not establish that the elements are strong enough to accomplish this task. Third, the embodiments of the Johnson invention shown in Figures 2-7 have no such outwardly extending elements, which would indicate that Johnson has no concern for maintaining the tip of the catheter in spaced relationship from the blood vessel wall and preventing contact therewith, and that the structure of the outwardly extending elements of

Figures 8-11 need be capable only of its stated function of obstructing blood flow, and not of keeping the tip of the catheter from contacting the wall of the vessel.

The second shortcoming of Johnson is with regard to the claim requirement that the tip immobilizing means is of such structure as to function "without substantially obstructing fluid flow of blood through the blood vessel, such that catheter failure due to stenosis or thrombosis at the catheter distal end is reduced." The function of the radially outwardly extending elements in the Johnson device is exactly the opposite for, as clearly is stated in the patent, they obstruct blood flow so as to "flow direct" the catheter through the vessel.

For the reasons set forth above, it is our opinion that Johnson does not anticipate the subject matter recited in claim 1, and the rejection is not sustained.

Claim 9 also requires that the tip immobilizing means maintain the catheter tip a spaced distance from the blood vessel wall and prevent it from contacting the wall. As the appellant has argued, this is not taught by Johnson nor is there reason to assume that this would be inherent in the

Johnson devices, as we explained above, and therefore the rejection of claim 9 as being anticipated by Johnson cannot be sustained. It then follows that the rejection of claims 10, 16, 30 and 31, all of which are dependent from claim 9, also will not be sustained. Johnson also does not teach the features of the wall contact members that are recited in claim 31.

Independent claim 20 sets forth a method of inserting a catheter which includes the steps of placing in a blood vessel a sheath insertion tube assembly that has a catheter inside and is provided with handles at its proximal end, maneuvering the assembly into selected position within the vessel, and withdrawing the sheath from the catheter while maintaining the catheter at a fixed position within the vessel. While Johnson mentions in passing that the catheter can be inserted by means of a sheath or needle (column 4, line 33), no information is provided regarding the structure of the sheath or the method in which it is used. In addition, claim 20 requires that there be a tip retainer assembly that contacts the wall of the vessel with a spring biased force that maintains the catheter tip anchored at a preselected location and held a selected

distance from the blood vessel wall to prevent the catheter tip from contacting the wall, which also is lacking in Johnson. In view of these shortcomings, Johnson does not anticipate the method recited in the appellant's claim 20. Nor, it follows, is the reference anticipatory of the subject matter added by dependent claim 21. The rejection of these two claims is not sustained.

Claim 22 is directed to an assembly adapted for insertion into a blood vessel. The assembly comprises a catheter means, an "introducer assembly means for aid in inserting the said catheter means," and a tip retainer assembly means located at the distal end of the catheter for retaining the tip portion "in a relatively fixed position within a blood vessel . . . in a spaced position from the blood vessel wall and preventing repeated contact of the tip portion of the catheter means with the blood vessel wall." While the sheath or needle disclosed by Johnson (column 4, line 33) can be considered to be introducer assemblies, for they aid in inserting the catheter into the blood vessel, for the reasons set forth above the Johnson fingers and wings do not meet the structural requirements of the tip retainer assembly as spelled out in

the claim. The claim language thus cannot be read on the Johnson catheters and the claim is not anticipated thereby. The rejection of independent claim 22 and dependent claims 23-25 and 27-29 is not sustained.

With regard to these dependent claims, we further note that Johnson fails to teach the sheath removal means recited in claim 25 or the spring structure of claims 27-29.

The method recited in claim 32 requires the insertion in a vessel of a catheter having tip retainer assembly at its distal end and a control assembly at its proximal end outside of the vessel, and manipulating the control assembly to deploy tip retainer assembly into abutting contact with the vessel wall with sufficient force to maintain the tip anchored at a preselected location and spaced from the vessel wall to prevent the catheter tip from repeatedly contacting the wall. The latter feature is not taught by Johnson, as we have explained above. The former one also is not taught by Johnson, in that the radially extending elements of Johnson are for the purpose of facilitating movement of the catheter through the vessel, rather than anchoring it at a selected position. The rejection of this claim is not sustained.

Claim 26, which is dependent from independent claim 22 by way of claims 23-25, stands rejected as being unpatentable over the combined teachings of Johnson and Corrigan, which was cited for its teaching of forming a catheter introducing sheath of a tearable membrane. Be that as it may, even considering Johnson in the light of 35 U.S.C. § 103,[3] the teachings of Corrigan fail to alleviate the shortcomings regarding maintaining the catheter spaced from the walls of the vessel, which have been explained above with regard to the subject matter recited in claim 22. This rejection is not sustained.

[3] The test for obviousness is what the combined teachings of the prior art would have suggested to one of ordinary skill in the art. See, for example, ***In re Keller***, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981).

SUMMARY

None of the rejections are sustained.

The decision of the examiner is reversed.

REVERSED

Irwin Charles Cohen Administrative Patent Judge	)	
Neal E. Abrams Administrative Patent Judge	)	BOARD OF PATENT APPEALS AND INTERFERENCES
John F. Gonzales Administrative Patent Judge	)	

tdl

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